EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

ADVANCED NEUROMODULATION SYSTEMS, INC.	§	
	§	
Plaintiff,	§	
v.	§	
	§	**Civil Action No. 4:04cv131**
ADVANCED BIONICS CORPORATION,	§	**(Brown)**
	§	
Defendant.	§	

EXPERT REPORT OF CHARLES DANIELS, PH.D. REGARDING THE CONSTRUCTION OF CLAIM TERMS IN U.S. PATENT NO. 6,216,045

I. BACKGROUND AND QUALIFICATIONS

1. I have been the President of Materials Performance Consulting, LLC since 2003. In that position, I consult on many polymer materials issues, including product and process diagnosis and resolution and structure property relationships.

2. From 1997 to 2003, I was President of Polymer Diagnostics, Inc. There, I oversaw research, testing, and consultation relating to polymer materials, including in applications such as medical devices, electronics, consumer goods, automotive products and construction.

3. From 1993 to 1997, I was Director of Technology at the Geon Company. From 1969 to 1993, I held a number of positions at Geon's predecessor, the BF Goodrich Company, including R&D Scientist, Manager of R&D, and eventually Director of R&D. In these various positions, I managed and was involved in research and development concerning different types of polymers.

4. I received a Ph.D. in Chemistry and Polymer Science from Case Western Reserve University in 1969. I also received an M.S. in Chemistry and Polymer Science

13. I understand that patent claims should be construed from the perspective of a person of ordinary skill in the field to which the patent relates. In my opinion, the person skilled in the field of the '045 patent would have at least a bachelors degree in polymer science, mechanical engineering or a related field or several years of experience with polymers used in medical devices. I am at least a person of ordinary skill in this art.

14. I expect to testify at the patent claim construction hearing in this case about my opinions as set forth below and the bases therefore. I reserve the right to supplement these opinions and will likely respond at the hearing to any opinions of ANS's experts regarding the construction of the '045 patent.

A. "the lead body is formed of a material having prescribed mechanical properties"

15. The first limitation of claims 1, 12 and 14 recites a "lead body formed of a material with prescribed mechanical properties." In my opinion, it is not possible to determine what is covered by this language.

16. The claims do not specify any properties of the lead body. The patent specification is also unclear as to which mechanical properties are prescribed. For example, in column 1 lines 15 to 20, the patent refers to "common requirements" for implantable leads, including "flexibility, strength, and durability" and refers to them as "prescribed characteristics." Later in the patent specification at column 3, lines 46 to 54, it discusses the properties of the lead body as follows:

> Spanning between electrodes **18** of the distal end **14** and terminals **16** of the proximal end **12**, body **22** is formed from a medical grade, substantially inert material, for example, polyurethane, silicone, or the like. While the specific material used for body **22** is not critical to the present invention, body **22** must be non-reactive to the environment of the human body, provide a flexible and durable (i.e., fatigue resistant) exterior structure for the components of lead **10**, and insulate adjacent terminals **16** and/or electrodes **18**.

While the properties listed in these two sections overlap, they are not identical. Nevertheless, for purposes of this report, I will assume that the lead body must be formed

20. None of the examples provided in the patent assist in understanding what specific types of lead body materials are covered by the claim language. For example, the patent states that "polyurethane, silicone, or the like" may be used. This language is very broad and could encompass materials that are chemically very different, such as pure silicone polymers, pure urethanes, combinations in between (e.g., co-polymers, blends of polymers), various rubbers and plasticized vinyls. These materials have significant variations in their mechanical performance, many of which would not be suitable for use in an implantable stimulation lead.

B. "insulative material having mechanical properties consistent with the material of the lead body"

21. Claims 1, 9, 12 and 14 each have one or more limitations that require "insulative material having mechanical properties consistent with the material of the lead body." This language is used in two different contexts. In the second and third limitations of claims 1, 12 and 14, it refers to the material between electrodes and between terminals. In the last limitation of claims 1, 12 and 14, as well as claim 9, it refers to material that is used to substantially fill an interior passage of the lead or to form a substantially solid portion of the lead.

22. In my opinion, the person of ordinary skill in my field would not understand what the language "insulative material having mechanical properties consistent with the material of the lead body" encompasses as used in either context.

23. The properties of the insulative material that must be "consistent with" the lead body material appear to be the "prescribed mechanical properties" referred to above for the first limitation of claims 1, 12, and 14 – *i.e.*, which I am assuming are non-reactivity to the human body, flexibility, durability, strength and insulative ability.

24. A skilled person would not understand in what circumstances a material is considered to have "consistent" non-reactivity to the human body, flexibility, durability, strength and insulative ability with another material. Once again, to a skilled person,

same mechanical properties" connotes differences but is unclear to what extent the mechanical properties of the two materials may vary. It is unclear which of these two possible meanings the patentees intended by the term "consistent with" or whether the patentees intended something else.

29. I have also considered the one example of a spacer material provided in the '045 patent to see whether that would assist me in determining what the patentees intended to cover by the language "insulative material having mechanical properties consistent with the material of the lead body." This example also compounded the lack of clarity in the claim language.

30. The patent identifies Bionate 75D from Polymer Tech. Group as an example of a spacer material. Bionate 75D is a highly engineered polyurethane copolymer. Attached as Exhibit C is information about this material. I would not consider this material to have similar mechanical properties as most polyurethanes or silicones, which are identified as examples of lead body materials in the patent.

31. Thus, in my opinion, for the claim language "insulative material having mechanical properties consistent with the material of the lead body" to have any meaning to the skilled person, it must be construed such that the insulative material has the same values (as that concept is understood in my field) for the specific mechanical properties I identified above (*i.e.*, hydrolytic stability, coefficient of friction, abrasion resistance, water absorption, skin and subcutaneous tissue sensitivity, flexural modulus, flexural strength, tensile modulus, ultimate tensile strength, ultimate elongation, hardness (durometer), tear strength, compression set, coefficient of linear expansion, conductivity, insulation resistance, dielectric resistance, and dielectric strength) as the lead body.

32. The file history supports this construction. In responding to a rejection based on U.S. Patent No. 4,379,462 to Borkan, the patent applicants stated that "medical grade epoxy does not have the mechanical properties of, for example, the polyethylene material of sheath (12) of Borkan."

E. "substantially solid"

37. Claim 12 refers to a lead region that has a "substantially solid cross section . . . ." Claim 14 refers to a lead portion "formed from a substantially solid, fused matrix of material . . . ." In my opinion, it would not be clear to a skilled person to what extent the region or portion must be solid to satisfy the "substantially solid" language. A skilled person would understand the term "solid" to mean that the region or portion has no internal cavity.

F. "fused matrix"

38. Claims 8 and 11 each recite insulative material that is a "fused matrix."

39. Claim 13 refers to a lead portion "wherein the materials(s) forming the first region . . . is a fused matrix."

40. Claim 14 refers to a lead portion "formed from a substantially solid, fused matrix of materials . . . ."

41. A skilled person would understand the term "fused matrix" to mean a material that is formed by melting and bonding of at least two other materials together.

G. "consistent mechanical characteristics"

42. Claim 14 refers to the stimulation portion of the lead formed from a "substantially solid, fused matrix of materials having consistent mechanical characteristics." In my opinion, a skilled person would not understand what mechanical characteristics are being referenced or how to determine whether such characteristics are "consistent" for the same reasons I set forth above for the claim language "insulative material having mechanical properties consistent with the material of the lead body." Moreover, it is not clear from the patent claim language whether the mechanical characteristics are the "prescribed mechanical properties" referred to earlier in the claim or some other set of characteristics.

EXHIBIT A

Charles A. Daniels, Ph.D.

Publications

1.) Thermodynamics of Polyisobutylene Solutions - I: Inter-action Parameters from Osmotic Pressure Measurements, J. Macromolecular Sci., Physics, B2(3), 449 (1968) with S. H. Maron.

2.) Thermodynamics of Polyisobutylene Solutions - II: Vapor Pressures and Polymer Order, J. Macromolecular Sci., Physics, B2(3), 463 (1968) with S. H. Maron.

3.) Thermodynamics of Polyisobutylene Solutions - III: Thermal Behavior and Polymer Order, J. Macromolecular Sci., Physics, B2(4), 743 (1969) with S. H. Maron.

4.) Thermodynamics of Polystyrene Solutions - I: Interaction Parameters and Polymer Order, J. Macromolecular Sci., Physics, B2(4), 743 (1969) with S. H. Maron.

5.) Thermodynamics of Polystyrene Solutions - II: Thermal Behavior and Glass Energies, J. Macromolecular Sci., Physics, B2(4), 769 (1969) with S. H. Maron.

6.) Thermodynamics of Poly-α-Olefin Solutions, J. Macro-molecular Sci., Physics, B4(1), 47 (1970) with S. H. Maron and P. J. Livesey.

7.) Thermodynamics of Polymethylmethacrylate Solutions, J. Macromolecular Sci., B6(1), 1 (1972) with S. H. Maron.

8.) Thermodynamics of Polypropylene Solutions, J. Macromolecular Sci., B4(2), 227 (1970) with S. H. Maron.

9.) Common Methods of Particle Size Analyses, J. Paint Technol., 47(604), 35 (1975) with E. A. Collins and J. A. Davidson.

10.) PVC Part I: Effect of Polymerization Temperature on Association, Second Virial Coefficients and Molecular Dimensions, J. Macromol. Sci., Physics, B10(2), 287 (1974) with E. A. Collins.

11.) Effect of Order on Rheological Properties of Poly(Vinyl Chloride) Melts, Polymer Sci. and Eng., 14(5), 356 (1974) with E. A. Collins.

24.) Relationship Between the Particle Size and Viscoelastic Properties of PVC Plastisols, with N. Nakajima, J. Appl. Polymer Sci., 25(9), 2019 (1980).

25.) Effect of Particle Size Distribution on the Gelation and Fusion Behavior of PVC Plastisols As Observed by Changes in Morphology and Viscoelastic Properties with N. Nakajima, E. R. Harrell and J. D. Isner, SPE ANTEC November, 1980.

26.) Physical Constants of PolyVinyl Chloride, in Polymer Handbook, E. A. Grulke and E. H. Immergut, Wiley, New York (1998) with E. A. Collins and D. E. Witenhafer.

27.) Modification of PolyVinyl Chloride, in Polymer Modification, Principles, Techniques and Applications, John J. Meister, ed., Marcel Dekker, New York (2000).

28.) Rubber Related Polymers in Rubber Technology, 3, 561, Maurice Morton, ed., Reinhold, New York (1987) with K. L. Gardner.

29.) PVC Handbook, co-editor with J.W. Summers and C.E. Wilkes, Hanser Publications, to be published in 2004.

Director of Technology, 1993-1997. Responsible for reorganizing and staffing polymer analytical organizations to ensure successful formation of the new Geon company upon its separation from the BFGoodrich Company. Selected key staff and facilities to support organizational and customer needs.

- Led organization in achieving national accreditation and ISO registration.
- Standardized all manufacturing QC laboratory procedures.
- Successfully resolved key environmental hazard assessment issues.
- Recruited and hired world-class key scientific assets that broadened the organization's skill sets.

B.F. Goodrich Company: One of the world's largest tire, rubber, plastics, specialty chemicals and aerospace companies.

Director of R&D, 1985-1993. Reported directly to the Division President, leading R&D programs for the Specialty Elastomers and Latex Division from 1985-1989, and BFG's largest operating unit, the Geon Vinyl Division, from 1989 to 1993. Responsible for the design and execution of all Research and Development programs, including the Vinyl Division"s new product programs and the Elastomers and Latex R&D and technical service programs. Recruited, hired and developed key technical resources to support divisions' sales, marketing and manufacturing initiatives.

- Achieved two US patents for new products.
- Increased product revenues 25% in the first year, representing 130% of target.
- Developed several new vinyl products, resulting in the commercialization of the industry's first heat resistant vinyl compounds.
- Responsible for $20M research budget.

Manager, R&D, 1975-1985. Led four key research groups in plastics characterization, general purpose and specialty elastomers and PVC resin technology that developed and introduced new vinyl resins for the film, automotive and construction markets.

- Improved reproducibility of elastomer manufacturing process from 40% to over 95% in two years.
- Restructured research efforts in each area; streamlined project management by instituting rigorous accountability procedures and project teams focused on well-defined objectives.
- Drove new efficiencies and quality measures, resulting in significant product uniformity, and more rapid development of new products by forming cross-functional teams with clear division objectives.

R&D Scientist, 1969-1975. Responsible for supporting company wide R&D efforts by utilizing modern polymer analytical methods to solve customer problems.

- Developed new polymer characterization methods for key BFG products.
- Led key technical initiatives on two company-wide strategic programs in developing technology to remove vinyl chloride from process streams and to solve critical performance issues delaying the transfer of new resin technology from R&D.
- Developed methods for prediction of process behavior of vinyl resins, a key component leading to BFG's worldwide licensing of monomer removal technology.
- Developed lab-scale methods and computer models to predict behavior of post polymerization behavior of vinyl resins in world-scale manufacturing plants.

Granted two US patents on new products and process technology

EXHIBIT C

Bionate®

Polycarbonate Urethane

- Good Oxidative Stability
- Good Biocompatibility
- Mechanical Strength
- Optical Properties
- Abrasion Resistance
- Extensive FDA Masterfile

Introduction

Bionate® *polycarbonate-urethane* is among the most extensively tested biomaterials ever developed. The Polymer Technology Group Incorporated acquired the license to manufacture this thermoplastic elastomer from Corvita Corporation (who marketed it under the name Corethane®) in 1996.

Carbonate linkages adjacent to hydrocarbon groups give this family of materials oxidative stability, making these polymers attractive in applications where oxidation is a potential mode of degradation, such as in pacemaker leads, ventricular assist devices, catheters, stents, and many other biomedical devices. Polycarbonate urethanes were the first biomedical polyurethanes promoted for their biostability.

Bionate materials have application restrictions. Please contact the PTG Sales Department for details.

▲ Top

Chemistry

Bionate® *polycarbonate-urethane* is a thermoplastic elastomer formed as the reaction product of a hydroxyl terminated polycarbonate, an aromatic diisocyanate, and a low molecular weightglycol used a a chain extender.

▲ Top

Dielectric Constant at 60 Hz	D150	5.0	4.8	4.5	3.7
Mold Shrinkage, 4.0" Disk (%)	D955	1-2	1-2	1-2	1-2
Mold Shrinkage, Flame Bar (%)	D955	0-3.0	0-3.0	0.5-2.0	0.5-2.0

▲ *Top*

Biological Test Results

The scope of Bionate PCU's tests—encompassing Histology, Carcinogenicity, Biostability, and Tripartite Biocompatiblity Guidance for Medical Devices—reassures medical device and implant manufacturers of the material's biocompatibility. This allows biomaterials decision makers the ability to choose an efficacious biomaterial that will add to the cost-effectiveness of the development of their device or implant. Below is a summary of the extensive biocompatibility testing conducted on Bionate PCUs, including its successful completion of a 2-year carcinogenicity study.

Biological Test	Results
Ames Mutagenicity	Non-mutagenic
Chronic Toxicity: USP Muscle Implantation	Macroscopic reaction not significant
Compliment Activation	Less activation of the compliment system than ePTFE
USP Cytotoxicity (MEM Elution)	Non-toxic
Hemolysis	Non-hemolytic
Humoral Immunological Study	No humoral (serological) immune response
USP Pyrogenicity	Non-pyrogenic
Platelet Deposition (*ex vivo* shunt)	No difference in thrombogenicity when compared to ePTFE control
Sensitization: Magnusson and Kligman	No dermal sensitization
Acute Systemic Toxicity	No significant systemic toxicity
USP Implantation Test: 7 days in rats	Macroscopic reaction not significant
Intracutaneous Toxicity	No significant irritation or toxicity
Carcinogenicity: 2 years in rats	Non-carcinogenic

Bionate is supplied in free-flowing pelletized or diced granular forms in moisture-proof bags. Because polyurethanes are hygroscopic, these materials should be stored in a relatively dry area between 60 and 90 °F. Ideally, the entire contents of the bag should be used at one time; however, if less is required, then only remove what is necessary and blanket the remainder under inert gas, such as dry nitrogen, in a resealed container.

▲ *Top*

Safety

Click on the link below to download a printable copy of the Material Safety Data Sheet (MSDS) for Bionate thermoplastic polycarbonate urethane (requires Adobe® Acrobat Reader®)

- Bionate MSDS

▲ *Top*

Home Materials

Updated 05.05.02

Bionate®

Polycarbonate Urethane

Home Materials

- Good Oxidative Stability
- Good Biocompatibility
- Mechanical Strength
- Optical Properties
- Abrasion Resistance
- Extensive FDA Masterfile

Introduction

Bionate® polycarbonate-urethane is among the most extensively tested biomaterials ever developed. The Polymer Technology Group Incorporated acquired the license to manufacture this thermoplastic elastomer from Corvita Corporation (who marketed it under the name Corethane®) in 1996.

Carbonate linkages adjacent to hydrocarbon groups give this family of materials oxidative stability, making these polymers attractive in applications where oxidation is a potential mode of degradation, such as in pacemaker leads, ventricular assist devices, catheters, stents, and many other biomedical devices. Polycarbonate urethanes were the first biomedical polyurethanes promoted for their

Linear Thermal Expansion (x10⁻⁵)		89.0/°F	89.3/°F	76.2/°F	51.8/°F
Melt Index (approx) g/10 min at 224 °C	D1238	(1200 g) 20.7	(1200 g) 9.2	(2160 g) 13.3	(5000 g) 17.8
Flexural Modulus, 1% Secant Modulus (psi)	D790	4160	6030	7000	260,000
Flexural Stress at 5% Deflection (psi)	D790	180	275	300	10,200
Dielectric Strength (V/mil)	D149	430	480	530	>625
Dielectric Constant at 60 Hz	D150	5.0	4.8	4.5	3.7
Mold Shrinkage, 4.0" Disk (%)	D955	1-2	1-2	1-2	1-2
Mold Shrinkage, Flame Bar (%)	D955	0-3.0	0-3.0	0.5-2.0	0.5-2.0

▲ *Top*

Biological Test Results

The scope of Bionate PCU's tests—encompassing Histology, Carcinogenicity, Biostability, and Tripartite Biocompatiblity Guidance for Medical Devices—reassures medical device and implant manufacturers of the material's biocompatibility. This allows biomaterials decision makers the ability to choose an efficacious biomaterial that will add to the cost-effectiveness of the development of their device or implant. Below is a summary of the extensive biocompatibility testing conducted on Bionate PCUs, including its successful completion of a 2-year carcinogenicity study.

Biological Test	Results
Ames Mutagenicity	Non-mutagenic
Chronic Toxicity: USP Muscle Implantation	Macroscopic reaction not significant
Compliment Activation	Less activation of the compliment system than ePTFE
USP Cytotoxicity (MEM Elution)	Non-toxic
Hemolysis	Non-hemolytic
Humoral Immunological Study	No humoral (serological) immune response
USP Pyrogenicity	Non-pyrogenic

Extruder Configuration

Parameter	Value
Length to Diameter Ratio	24:1
Compression Ratio	2.5:1 to 3.5:1
Cooling Water Temperature	18-20 °C (64-68 °F)

▲ Top

Storage

Bionate is supplied in free-flowing pelletized or diced granular forms in moisture-proof bags. Because polyurethanes are hygroscopic, these materials should be stored in a relatively dry area between 60 and 90 °F. Ideally, the entire contents of the bag should be used at one time; however, if less is required, then only remove what is necessary and blanket the remainder under inert gas, such as dry nitrogen, in a resealed container.

▲ Top

Safety

Click on the link below to download a printable copy of the Material Safety Data Sheet (MSDS) for Bionate thermoplastic polycarbonate urethane (requires Adobe® Acrobat Reader®)

- Bionate MSDS

▲ Top

Home Materials

Updated 05.05.02

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION
- - - - -

ADVANCED NEUROMODULATION SYSTEMS, INC.,
Plaintiff,
-v-
ADVANCED BIONICS CORPORATION,
Defendant.

Civil Action No. 4:04CV131 (Brown)

- - - - -

VIDEOTAPED DEPOSITION OF CHARLES DANIELS, PH.D.
Friday, February 4, 2005
- - - - -

Videotaped deposition of CHARLES DANIELS, PH.D., called by the Plaintiff for examination under the Federal Rules of Civil Procedure, taken before me, Grace M. Hilpert, Registered Professional Reporter, a Notary Public in and for the State of Ohio, at the offices of Jones Day, North Point, 901 Lakeside Avenue, Cleveland, Ohio 44114, commencing at 9:28 a.m., the day and date above set forth.

- - - - -

CORSILLO & GRANDILLO
COURT REPORTERS
700 City Club Building
Cleveland, Ohio 44114
216-523-1700

- - - - -

APPEARANCES:

On Behalf of the Plaintiff:

B.C. Boren, Esquire
Christopher W. Kennerly, Esquire
Baker Botts, LLP
2001 Ross Avenue

Dallas, Texas 75201-2980

On Behalf of the Defendant:

Jennifer A. Sklenar, Esquire
Howrey Simon Arnold & White
550 South Hope Street, Suite 1400
Los Angeles, California 90071

- - - - -

ALSO PRESENT:

Steve Henschel, Videographer

- - - - -

INDEX

- - - - -

THE VIDEOGRAPHER: Today's February 4, 2005. We're on the record at 9:28 a.m.

- - - - -

CHARLES DANIELS, PH.D.

called by the Plaintiff for examination under the Federal Rules of Civil Procedure, after having been first duly sworn, as hereinafter certified, was examined and testified as follows:

- - - - -

EXAMINATION

- - - - -

BY MR. BOREN:

Q Dr. Daniels, my name is B.C. Boren. You and I met just a few moments ago.
You do, in fact, have a Ph.D., do you not?
A Yes, I do.
Q What other degrees do you have?
A Master's degree, an MS, and a Bachelor's degree, a BA.
Q What was your Bachelor's degree in?
A Chemistry.
Q And your Master's?

A Polymer science and chemistry.
Q And your Ph.D.?
A Polymer science and chemistry.
Q What is polymer science?
A The study of very large molecules. For better or for worse, that's the best description.
Q What is a polymer?
A I'm sorry?
Q What is a polymer?
A A polymer is a long chain molecule that consists of a number of repeating units that could reach molecular weights of several hundred thousand. Generic term for polymers is plastics.
Q Are polymers typically organic, are the molecules organic molecules, are they synthetic or are they one or the other?
MS. SKLENAR: Objection.

different from what I have just described to you --

MS. SKLENAR: Objection. Form.

19

Q -- if it is?
A It is. The rigid PVC that you describe for pipe is a very simple formulation. It is made to sheath wiring in a conduit or conduct or carry water in a piping application.
The flexiblized PVC is one in which ingredients are added to it so that rather than being a stiff rigid material, it's capable of being flexed, capable of being bent. It can be made transparent. It can be made into colored formulations.
Common application for which is, although it's not this particular one, insulation for wire is a classification of flexible PVC.
Q Do you have now or have you ever had any kind of relationship with Advanced Bionics?
A No, I have not.
Q Do you have now or have you ever had a relationship with a company called Boston Scientific?
A Polymer Diagnostics did work for Boston Scientific, however, not in this area.
Q In what area?

20

A Other types of medical devices but not neurostimulator leads.
Q Did Polymer Diagnostics or any of the companies that you ever worked for do any work on neurostimulator leads?
A Not to my knowledge.
Q So prior to the time that you were hired in this case, you had never had the opportunity or the occasion to consider what materials might be appropriate for a neurostimulator lead?
A That's correct.
Q Is that something you feel like you could do?

MS. SKLENAR: Objection. Form.

A I think I'm capable of commenting on the appropriateness of certain materials for use in implantable devices. Whether they would be specific for neurostimulator leads, obviously, there's a specific set of requirements for that particular application that might be different from other implantable devices.
Q In fact, one of the things that you do

and you have done in your profession is to know what you don't know and to refer clients or customers to experts who might know more about a given field than yourself; is that correct?

26

A I'm not sure I know what you're --
Q That's because it was a really unartfully asked question.
A I know.
Q The problem isn't yours. It's mine.
A Okay.
Q Did you consult any resources to determine what materials had successfully been used in the past in neurostimulator devices?
A No.
Q Would you agree with me that there surely must be people out there who have some experience with these specific kinds of materials and would likely know what kinds of materials had been used successfully in the past in these applications?
A May I restate your question?
Q Sure.
A You're asking me, are there people in the world of neurostimulator leads that exist that would know what materials are being used in this application?
Q Yes.
A Certainly.

27

Q But you're not one of those people?
MS. SKLENAR: Objection. Form.

A I am not one of those people, have not developed a neurostimulator lead.

Q And you haven't talked to any of those people in preparing for your testimony?

A No.

MR. BOREN: Let's go off the record for a second.

THE VIDEOGRAPHER: Off the record.

(Discussion off the record.)

THE VIDEOGRAPHER: Back on the record.

Q Who prepared the first draft of Exhibit 1?

A The process was as follows: I had an opportunity to examine the patent and the patent file.

Q And the patent, just for the record?

A The '045.

Q Is the '045 patent?

A Yes, sir. I was asked to give comments and opinions about the language and

terminology that we've described.

I asked, because of constraints on my time, to have Jennifer's firm capture my comments, send them back to me for review, which we did. And I altered that so that I was certain that the opinions would represent my statements.

Q Then what?

understanding of virtually all aspects of the devices and their design," et cetera, correct?

38

A That's what it says.
Q On what basis do you criticize that statement?
A It would be very unusual, and I don't believe this ever existed in my experience, for product development teams consisting of a group of experts, for each and every one of those experts to fully understand and become expert in each of the fields represented by the other experts on a team.
They would contribute their own expertise, they would certainly learn things from one another, but they certainly wouldn't be considered experts in those other areas after having worked on those teams.
Q I don't find the word "expert" anywhere in that first full paragraph of page 9. Do you?
A No, I don't.
Q Mr. Robinson does say understanding which -- let me just ask you. Do you believe understanding something is the same thing as being an expert in it?
A I'm sorry. He says, "Detailed understanding of virtually all experts."

39

Q "Aspects"?
A Correct. That's not just understanding in my interpretation.
Q You believe that -- what do you believe it is?
A I believe it is -- he is indicating that each person on the team could take the place of others on the team, in terms of their expertise, after having been exposed to this team environment.
Q But your basis for criticism of his statement does not come from having served on such an implantable stimulation team yourself, correct?
A Correct.
Q Because you have never done that?
A That's correct.
Q If we can believe what Mr. Robinson says in his report, he has done that, correct?
A That's correct.
Q What is the field of the '045 patent?
A The field of the '045 patent?
Q Yes.
A The construction of and the function of

a neurostimulator lead.
Q You have never constructed a neurostimulator lead, have you?
A No.
Q You have never participated in the

construction of a neurostimulator lead, have you?

A That's correct.

MR. BOREN: Let's take a short break.

THE VIDEOGRAPHER: Off the record at 10:21.

(Recess had.)

THE VIDEOGRAPHER: Back on the record at 10:34.

Q Dr. Daniels, if you would turn to your report in this matter, which is Exhibit Number 1. In paragraph 10 on page 2 of Exhibit Number 1 you tell us that you're compensated at $400 per hour for time spent providing deposition or other testimony, correct?

A Correct.

Q Is it true that you're being paid $400 per hour for your time today?

A Yes.

Q How much have you been paid so far by your client, either AB or the lawyers?

A I have submitted invoices but have not yet been paid.

Q How much total have you submitted in invoices?

A Approximately $3,000.

Q How much additional time have you incurred that you have not yet billed, do you

patent are too broad or too vague, it is possible that the validity of the patent might be challenged, but that's not my bailiwick.

Q But you do offer a number of opinions in Exhibit Number 1 to the effect that a skilled person wouldn't understand given terms, correct?

A That is correct.

Q One of the problems -- one of the terms

that you have problems with is the term "consistent", correct, page 6, paragraph 25?

MS. SKLENAR: Objection. Form.

A In paragraph 25, page 6 I did state that, "A skilled person would not understand from the language 'consistent with.'"

Q What's your basis for that opinion?

A It is too vague a term.

Q Too vague for whom?

A Someone skilled in the art.

Q Which art?

MS. SKLENAR: Objection. Form.

A You're talking about the lead body materials, which are comprised of plastics or polymers, and someone skilled in the art of plastics or polymers would ask for something more definitive than the term "consistent with" when describing the properties of one

or more materials.

Q Do you know whether someone skilled in the art of implantable leads would require more information to understand "consistent with"?

MS. SKLENAR: Objection. Form.

A I don't know that. I would hope so.

Q But you don't know, correct?

A I don't know.

Q Did you look up "consistent" in the dictionary?

A Not recently.

Q You didn't do it for purposes of this case?

A No.

Q So you didn't consider the plain and ordinary meaning of the term?

MS. SKLENAR: Objection. Form.

A Consider it?

Q "Consistent."

A I'm sorry. Consider the term?

Q Yes.

A Certainly I considered the term.

Q My question was more specific. Did you consider the plain and ordinary meaning of the term?

A Yes.

Q What is the plain and ordinary meaning

A Go ahead, please.
Q You said you could compound SBR rubber in such a way that it would have similar chemical and mechanical properties to another substance. Do you recall saying that?
MS. SKLENAR: Objection. Form.
Q I don't remember what the other substance was because it was very technical sounding to me.
A Okay.
Q I'm trying to first understand why you used the word "similar," and in my attempt to understand that, I want to ask you what similar means in that context?
MS. SKLENAR: Objection. Form.
A I meant, as I said here, you could take

and compound these and have the same properties.
Q So you just didn't mean to say "similar"?
MS. SKLENAR: Objection. Form.
A I did not mean to say "similar".
Q What is the difference between same and similar?
A Similar is in my mind close but not exact. Same is identical.
Q On several occasions in your report you

take issue with the term "substantially", do you not?

A I do.

Q Why?

A I'm not sure what it means in terms of defining what substantially filled or substantially surrounds or substantially isodiametric means.

Q Let me ask you. What would exactly isodiametric be?

A It would mean exactly isodiametric.

Q That's what we call a tautology. Let me break it down.

Isodiametric means what?

MS. SKLENAR: Objection. Form.

A It means having the same diameter.

Q For the full length of the object, whatever it is, correct?

A If that's where you're using it, yes.

Q That's certainly where it's being used in this case, is it not?

A Okay. Let's choose that as an example.

Q I'm going to choose another example because it's a little easier to understand.

The leads that we're talking about here are dozens of centimeters long in some cases, are they not?

A Yes, they are.

Q Let's move over to a garden hose, which

isodiametric for now.

How do you know what isodiametric means when you know as a matter of physics that anything made up of molecules is going to comprise different diameters depending on where the measurement is taken?

A You would make the judgment on what isodiametric meant or substantially isodiametric meant in the context in which it was used.

Q You will have to explain that to me because I don't get it.

A Your example was isodiametric at the molecular level. Okay?

Q Yes.

A I could say, well, what about isodiametric at the gross surface diameter level. Two different contexts.

Q Different measurement scales?

A Absolutely.

Q Back to my garden hose example. If one purchased a three-quarter inch diameter garden hose in the real world, one would ordinarily expect that three-quarter inch

59

garden hose to vary some along its length but to be generally three-quarters of an inch in diameter, wouldn't one?

A There would be some variation.

Q Variation on a much larger level than a molecular level, fair enough?

A Fair enough.
Q The same thing, now we're going to a lead which is much, much smaller than a garden hose, correct?
A Correct.
Q In fact, can you give us a sense of how small these leads are?
A I believe in your -- in the patent, which I don't have a copy in front of, there are some dimensions actually given in one of the paragraphs.
Q There are.
A Tenths to hundredths of centimeters, I believe reported.
Q To the lay person it's actually a very, very small diameter, isn't it?
A To the lay person, that's true. That is true.
Q Have you ever seen one of these?

A Not up close.
Q Have you ever seen one far away?
A It would be harder to see far away than up close, wouldn't it, given the dimensions. No, I have not actually observed a neurostimulator lead.
Q They're little bitty around, you're right about that. I don't think little bitty is in the patent.
A I thought maybe it was a new technical term.

25 A Yes, I see that.

70

1 Q And, again, in paragraph 24, the same
2 term, "substantially round." Do you see
3 that?
4 A Yes, I see that.
5 Q And, again, in paragraph 32 on page 3,
6 there's a reference to a substantially round
7 pad, is there not?
8 A Yes, there is.
9 Q And then, again, in paragraph 32 on
10 page 4 near the top, there's a reference to
11 -- two references to substantial -- near the
12 top of page 4, also paragraph 32, there are
13 two references to the term "substantially
14 covering." Do you see those in the first
15 half of that partial paragraph?
16 A Fifth sentence down or so, "second
17 surface with a pad substantially covering"?
18 Q Yes, sir. It's in the second line as
19 well.
20 A I'm sorry. "In the first surface of
21 the pad substantially covering" --
22 Q Do you see two references to
23 "substantially covering" in that paragraph?
24 A Yes.
25 Q In paragraph 15 of the claims, claim

71

1 15, the terms "substantially flat" and
2 "substantially round" both appear, do they
3 not?

A They do appear.
Q Would you agree with me that there's a possibility that people who are skilled in the art of implantable medical devices might attach a meaning to "substantial" or "substantially" that you might not be aware of?
MS. SKLENAR: Objection. Form.
A My answer to the question is that that is still a vague and general term. It does not, in my mind and, again, not having read this document, so I can't be sure where they're applying this term, it's very difficult at first glance to understand what their meaning is.
MR. BOREN: That really wasn't my question. I'm going to object to that as non-responsive.
Q Would you agree with me, would you not, that it's possible that those skilled in the art of implantable medical devices might

attach a meaning to "substantially" of which you are unaware?
A Anything is possible.
Q You need to answer that question yes or no.
A Yes, it is possible.
Q I may have asked you this. If I did, I apologize.